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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,751	07/20/2001	Paul Kenneth Rand	PG3604USW	8846

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DAVID J LEVY, CORPORATE INTELLECTUAL PROPERTY  
GLAXOSMITHKLINE  
FIVE MOORE DR., PO BOX 13398  
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

PATEL, MITAL B

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/889,751	<b>Applicant(s)</b> RAND, PAUL KENNETH	
	<b>Examiner</b> Mital B. Patel	<b>Art Unit</b> 3743	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 November 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-8 and 10-42 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-42 is/are allowed.
- 6) ☒ Claim(s) 1,3-8 and 10-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Amendment/Arguments*

1. Applicant's arguments, filed 11/18/04, with respect to the rejection(s) of claim(s) 1, 3-8, 10-22, 26-40 and 41-43 under 35 U.S.C. 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Rigney et al (US 3,654,890).

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-8, 10-15, and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Rigney et al (US 3,654,890).

4. **As to claim 1**, Rigney teaches a medicament cartridge **1** for use in an inhalation device comprising a carrier **2** having a substantially planar first face (**the Examiner considers the carrier to be substantially planar and having a first face when viewing the carrier from the side**) and a plurality of medicament retainers **7** defined by openings in said first face, said openings being directed in a common direction and being positioned upon a single spiral path arrangement along said first face.

5. **As to claim 3**, Rigney teaches a medicament cartridge wherein the carrier is substantially rigid (**See Figs. 1**).

6. **As to claim 4**, Rigney teaches a medicament cartridge wherein the carrier is circular in shape and is rotationally mountable (**See Figs. 1 and Col. 2, lines 47-66**).
7. **As to claim 5**, Rigney teaches a medicament cartridge wherein each medicament retainer comprises a pocket (**that formed by the aperture** ).
8. **As to claim 6**, Rigney teaches a medicament cartridge wherein a seal is provided to each pocket (**See Fig. 2**).
9. **As to claim 7**, Rigney teaches a medicament cartridge wherein the seal comprises a sealing tape **11** positioned upon said planar first face covering said openings and arranged along a flat spiral path and wherein each pocket is accessible by progressive removal of the tape from the spiral path.
10. **As to claim 8**, Rigney teaches a medicament cartridge wherein each medicament carrier comprises a hole **7** in the carrier.
11. **As to claim 10**, Rigney teaches a medicament cartridge wherein the carrier is elongate, storable in a plane in a flat spiral configuration wherein said openings are directed in said common direction and said elongate carrier is extendable from the plane of flat spiral configuration (**See Fig. 1**).
12. **As to claim 11**, Rigney teaches a medicament cartridge wherein the medicament retainers are serially arranged along the elongate carrier (**See Fig. 1**).
13. **As to claim 12**, Rigney teaches a medicament cartridge wherein each medicament retainer comprises a cavity **7** in the elongate carrier.
14. **As to claim 13**, Rigney teaches a medicament cartridge wherein a seal is provided to each cavity.

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15. **As to claim 14**, Rigney teaches a medicament cartridge wherein the seal comprises a sealing tape **11** and each cavity is individually accessible by peelable removal of the sealing tape.

16. **As to claim 15**, Rigney teaches a medicament cartridge wherein each medicament retainer is sized to retain a single dose of medicament (**See Fig.1**).

17. **As to claim 17**, Rigney teaches a medicament cartridge wherein the medicament dose is applied to the carrier by wet or dry printing methods. It should be noted that the claim is directed to a device/apparatus and as such patentable weight is given to the end product and not the process. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

18. **As to claim 18**, Rigney teaches a medicament cartridge wherein the medicament is present in one or more of the medicament retainers (**See Fig. 1**).

19. **As to claim 19**, Rigney teaches a medicament cartridge for use in an inhalation device comprising an elongate carrier **2,3** having a substantially planar first face having plurality of medicament doses thereon, wherein the doses are in a single spiral path arrangement along the first face (**See Fig. 1**).

***Claim Rejections - 35 USC § 103***

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

22. Claims 16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rigney et al (US 3,654,890).

23. **As to claim 16**, Rigney teaches essentially all of the limitations except for the medicament cartridge having from 60 to 500 medicament retainers. However, the number of retainers will depend on the medicament along with the dosing requirements for each patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the appropriate amount of medicament retainers based on the medicament and dosing requirements of the individual.

24. **As to claim 20**, Rigney teaches a medicament cartridge for use in an inhalation device comprising an elongate carrier 2,3 comprising an upper surface and first and second side surfaces having a plurality of medicament doses thereon wherein said

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elongate carrier is storable in a flat spiral configuration wherein said upper surface is presented substantially in a single plane and is in use, extended from said plane (**See Fig. 1**). It should be noted that Rigney is silent to the side surfaces being narrower than said upper surface. However, Applicant has not provided a reasoned statement as to how the side surfaces being narrower than the upper surface provides an advantage, solves a stated problem, or provides an unexpected result. As such, one of ordinary skill in the art would expect the elongate carrier of Rigney to work equally as well as that of Applicant's since the function of the carrier is not altered by the dimensions of its surfaces.

***Allowable Subject Matter***

25. Claims 21-42 are allowed over the prior art of record.


26. The following is a statement of reasons for the indication of allowable subject matter: As to claims 21, 26, 33, and 41, the prior art of record does not teach nor render obvious the overall claimed combination of an inhalation device having a housing having an air inlet, an air outlet, and an airway therebetween.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 571-272-4802. The examiner can normally be reached on Monday-Friday (11:00-7:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mital B. Patel  
Examiner  
Art Unit 3743